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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,191	09/14/2003	Shyam K Gupta	2190	
34820 SHYAM K. G	7590 05/16/2007 [JPTA		EXAM	INER
BIODERM RESEARCH 5221 E. WINDROSE DRIVE			CHANNAVAJJALA, LAKSHMI SARADA	
SCOTTSDALI			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
		•	05/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Commence	10/605,191	GUPTA, SHYAM K				
Office Action Summary	Examiner	Art Unit				
	Lakshmi S. Channavajjala	1615				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DATE of the may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period we failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION (6) In no event, however, may a reply be time till apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE!	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 29 Ja	nuary 2007	•				
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· · · · · · · · · · · · · · · · · · ·						
•	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>14-28</u> is/are pending in the application.						
• • • • • • • • • • • • • • • • • • • •	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) 14-28 is/are rejected.						
7) Claim(s) is/are objected to.	· · · ——					
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9) The specification is objected to by the Examine	r					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119	•					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau	ı (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.						
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•						
Attachment(s)	Λ <b>Π</b>	(DTO 440)				
1) Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  A) Interview Summary (PTO-413)  Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	5)  Notice of Informal P 6)  Other:	atent Application				

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## **DETAILED ACTION**

Receipt of amendment and response dated 1-29-07 is acknowledged.

Claims 1-13 have been canceled. New claims 14-28 have been added.

The following rejection of record has been maintained:

## Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 14-15, 19, 23, 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4, 525,343 to Raaf.

Raaf discloses a tooth and a mouth care agent in the form of toothpaste (meets instant claim 11), mouthwash, mouth spray or tooth powder etc., an anti-inflammatory agent, hesperidin ascorbate (abstract), which meets the instant anti-inflammatory of claim 14 and claim 23. In particular, example 3 and example 5 recite zeolite, which is sodium aluminum silicate and thus read on the instant divalent metal cation and zeolite anion pair. In addition the examples recite allantoin, carboxymethyl cellulose and silica, all of which read on the limitations of instant claims 26-28 respectively. Further, the above examples recite water that reads on the instant carrier base of claim 14. Instant claims recite the limitation "for treatment of diaper", which is an intended use and hence carries no patentable distinction.

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Claim 14, 16, 17 is rejected under 35 U.S.C. 102(e) as being by anticipated by 2. US 4,826,676 to Gioffre et al (Gioffre).

Gioffre discloses an anticarcinogenic and anticalculus composition comprising zeolitic zinc cations, a polishing agent, a source of fluoride ions (col. 2, L 21-30). The reference discloses a toothpaste composition comprising the zinc zeolite (last two lines of col. 2). Example 2 describes the aqueous solutions of the composition. Thus, Gioffre anticipates instant claims. Instant claims recite the limitation "for treatment of diaper", which is an intended use and hence carries no patentable distinction.

Claims 14-15, 20, 27 and 28 are rejected under 35 U.S.C. 102(e) as being by 3. anticipated by US 6,638,521 to Dobrozsi.

Example 6 of Dobrozsi shows a pharmaceutical composition comprising natural honey (reads on anti-inflammatory), sodium saccharin (sugars), magnesium aluminum silicate clay, natural menthol and oil of eucalyptus (both read on anti-inflammatory agents as well as plant extracts), water (instant carrier) and other components. Thus, Dobrozsi anticipates instant claims. Instant claims recite the limitation "for treatment of diaper", which is an intended use and hence carries no patentable distinction.

## Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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4. Claim 20-22 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,525,343 to Raaf.

Raaf does not expressly state if the composition is in the form of an emulsion, microemulsion or suspension, powder or ointment etc. However, depending on the components of the composition, preparing an appropriate emulsion or suspension that is suitable for delivery i.e., as toothpaste or a mouth care composition (such as gel or ointment) is routinely practiced in the art. Hence it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to choose an appropriate form of preparing toothpaste or other oral care composition without affecting the efficacy of the individual components of the composition.

5. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4, 525,343 to Raaf in view of US 4,826,676 to Gioffre et al (Gioffre).

Instant claims are directed to a zeolite anion pair wherein the metal cation is chosen from magnesium, zinc etc. Raff, discussed above, fails to teach a toothpaste with the claimed cations and instead a sodium alumiosilicate.

Gioffre, discussed above, teaches zinc-zeolite in a toothpaste composition for good polishing and abrasive effects. The composition of Gioffre is also in the form of toothpaste and comprises components such as fluoride compounds, cellulose, silica etc., similar to that of Raaf. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add zinc zeolite of Gioffre in the composition of Raaf because both the references are directed to tooth paste compositions contains

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fluoride antimicrobials and alumiosilicate compounds and because Gioffre suggests that zinc zeolite ion exchange pair is not only biologically active but also is an excellent abrasive and a polishing agent to remove dental plaque. Therefore, a skilled artisan would have expected to impart the above dental plaque abrasive and polishing effect to the toothpaste composition of Raaf by adding the zinc zeolite ion pair of Gioffre.

6. Claims 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,638,521 to Dobrozsi. as applied to claims 14-15, 20, 27 and 28 above, and further in view of US 6,264,995 to Newmark et al.

Dobrozsi, discussed above, fails to teach ginger extract as anti-inflammatory agent, which claimed in the instant application.

Newmark teaches herbal anti-inflammatory composition comprising several plants and herbal extracts as anti-inflammatory agents. The herbal extracts are obtained sources such as ginger, rosemary, oregano etc (table I). Newmark also teaches administering the anti-inflammatory herbal extracts both topically as well as orally for an effective anti-inflammatory as well as antioxidant, free radical scavenging action (col. 6, L 50-60). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add the ginger extract of Newmark as antioxidant in the composition of Dobrozsi because Newmark teaches that the ginger extract not only possesses anti-inflammatory but also an antioxidant property. Hence, a skilled artisan would have expected both anti-inflammatory and also an antioxidant property.

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7. Claims 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4, 525,343 to Raaf, as applied to claims 14-15, 23, 26-28 above, and further in view of JP 06065036.

Raaf discussed above, fails to teach the claimed quaternary ammonium cation and zeolite ion pair in the toothpaste composition. Raaf instead teaches a sodium zeolite (examples).

JP discussed above teaches toothpaste and other oral care compositions comprising organosilicone quaternary ammonium together with an alcohol such as ethanol. JP suggests that the quaternary ammonium zeolite is very effective in suppressing the teeth coloring, sterilizing and removing microorganisms in the oral cavity and also in manifesting plaque control. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add the quaternary ammonium zeolite of JP in the toothpaste composition of Raaf because of the above benefits to the teeth and oral cavity described JP. A skilled artisan would have expected to reduce inflammation as well as provide protection from plaque, microorganism and teeth coloring.

## Response to Arguments

Applicant's arguments filed 1-29-07 have been fully considered but they are not persuasive. Applicants argue that instant claims have been amended to recite the limitation "for the treatment of diaper rash", which is an intended use and carries no

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patentable weight. Instant claims are only directed to a composition, which reads on the

prior art composition, irrespective of the use of the composition. Accordingly, even

though the cited references mostly teach oral care or dental care read on the claimed

limitation. Hence the rejections have been maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time

policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615 May 11, 2007

AKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER